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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,989	01/29/2001	Alexandros Makriyannis	UCON/150/PC/	1360

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ALIX YALE & RISTAS LLP  
750 MAIN STREET  
SUITE 1400  
HARTFORD, CT 06103

EXAMINER

OSTRUP, CLINTON T

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 01/26/2004

13

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/701,989

Applicant(s)

MAKRIYANNIS ET AL.

Examiner

Clinton Ostrup

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10/08/03.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 8-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 January 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_. 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

Claims 1-14 are pending in this application.

### ***Priority***

Priority to US Provisional Application Number 60/088,568 filed June 9, 1998 and PCT/US99/12900, filed June 9, 1999 has been acknowledged.

### ***Election/Restrictions***

This application contains claims 8-14 drawn to an invention nonelected with traverse in Paper No. 9, filed January 21, 2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 8-14 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9, filed January 21, 2003.

## **Response to Applicant's Arguments/Amendment**

### ***Claim Rejections***

#### ***New Matter Rejection - 35 USC § 112, First Paragraph***

Although claims 8-14 have been withdrawn from consideration, as being drawn to a non-elected invention, the examiner objected to claim 8 and rejected claims 8-14 as containing new matter, in the interest of compact prosecution. Applicant's amendment and arguments filed October 8, 2003, Paper No. 12, to the objection of claim 8 and rejection of claims 8-14 under 35 U.S.C. 112, first paragraph, have been fully considered and deemed persuasive. Therefore, the said objection and rejection have been withdrawn.

### ***Double Patenting***

Applicant's lack of argument in the amendment filed October 8, 2003, Paper No. 12, to the provisional obvious-type double patenting rejection of Claims 1-7 as being unpatentable over claims 1-8 and 12-19 of copending Application No. 09/328,742 has not made the rejection moot. Therefore the said rejection has been maintained. Applicants have not provided any argument as to why the instant claims 1-7 are not obvious over Application No. 09/328,742; therefore, the said rejection has been MAINTAINED.

Although Applicants may hold their response to this rejection in abeyance until allowable subject matter has been indicated, all reasonable rejections are made.

### ***Claim Rejections - 35 USC § 102***

Applicant's amendment and arguments filed October 8, 2003, Paper No. 12, to the rejection of claims 1, 3, 5-7 under 35 U.S.C. 102(a) as being anticipated by Calignano et al., Potentiation of Anandamide Hypotension by the Transport Inhibitor, AM404, European Journal of Pharmacology, Oct 15, 1997, 337 (1) R1-2 have been fully

Art Unit: 1614

considered and deemed persuasive, based on Applicant's amendment, specifically excluding the compound disclosed by Calignano et al; therefore, the said rejection has been withdrawn.

Applicant's amendment and arguments filed October 8, 2003, Paper No. 12, to the rejection of claims 1, 3, and 5-7 under 35 U.S.C. 102(a) as being anticipated by Beltramo et al., Functional Role of High-Affinity Anandamide Transport, as Revealed by Selective Inhibition, Science, August 22, 1997, 227 (5329) 1094-7 have been fully considered and deemed persuasive, based on Applicant's amendment, specifically excluding the compound disclosed by Beltramo et al; therefore, the said rejection has been withdrawn.

### **MAINTAINED CLAIM REJECTIONS**

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

Art Unit: 1614

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 and 12-19 of copending Application No. 09/328,742. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to compounds and methods of inhibiting the transport of anandamide in an individual or animal by administration of said compounds to said individual or animal. The compounds and methods of administering said compounds overlap one another in the conflicting claims and/or are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### **NEW CLAIM REJECTIONS**

#### ***Claim Rejections - 35 USC § 102***

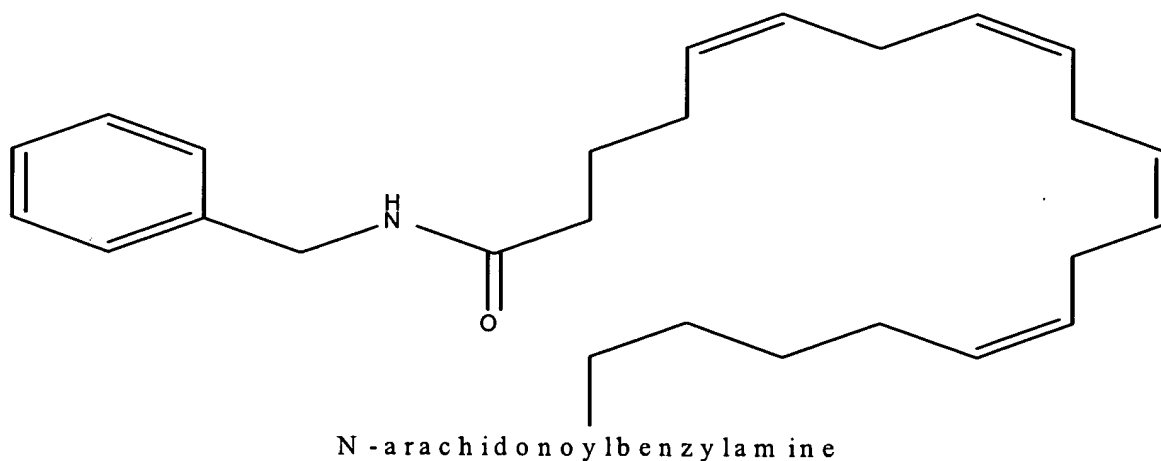
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 3, and 5-6 are rejected under 35 U.S.C. 102(a) as being anticipated by Hillard et al., Accumulation of N-Arachidonoyl ethanolamine (Anandamide) into Cerebellar Granule Cells Occurs via Facilitated Diffusion. Journal of Neurochemistry, August 1997. See: abstract; page 634, col. 1, Table 1; and page 637, col. 1, first full paragraph.

Hillard et al., teach N-arachidonoylbenzylamine as competing for anandamide and that anandamide is accumulated by a protein mediated transport process that has characteristics of facilitated diffusion. N-arachidonoylbenzylamine has the following structure:



and meets the structure of instant claims 1, 3, and 5-6, when Y is (-C(O)-NH-); and Z is aryl.

Thus Hillard et al, clearly anticipate instant claims 1, 3, and 5-6.

### **Conclusion**

Note: A method of inhibiting transport of anandamide in an individual or animal comprising administering to the individual or animal, in need thereof, a therapeutically effective amount of the elected compound on page 5, lines 6-7, in Paper No. 9, filed

Art Unit: 1614

January 21, 2003, appears to be allowable over the prior art and a claim drawn to said method will be considered favorably.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (703) 308-3627. The examiner can normally be reached on 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.



Art Unit: 1614

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Clinton Ostrup  
Examiner  
Art Unit 1614

A handwritten signature in black ink, appearing to read 'Frederick Krass', with a long horizontal line extending to the right.

Frederick Krass  
Primary Examiner  
Art Unit 1614

A handwritten signature in black ink, appearing to read 'Frederick Krass'.